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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,978	04/25/2001	Susana Salceda	DEX-0172	3638

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LICATA & TYRRELL P.C.
66 E. MAIN STREET
MARLTON, NJ 08053

EXAMINER	
AEDER, SEAN E	
ART UNIT	**PAPER NUMBER**
1642	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/763,978	SALCEDA ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,21-28 and 35-49* is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,21-28 and 35-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Request for Continued Examination

The request filed on 3/28/07 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/763,978 is acceptable and a RCE has been established. An action on the RCE follows.

Claims 14, 21-28, and 35-49 are pending and are currently under consideration.

Response to Arguments

35 USC § 101 and § 112, first paragraph, (Utility and Enablement Rejections)

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 21-28, and 35-49 remain rejected under 35 U.S.C. 101, because the claimed invention is not supported by either a substantial utility or a well established utility, for the reasons stated in the Office Action of 7/28/06 and for the reasons set-forth below. Further, claims 14, 21-28, and 35-49 remain rejected under 35 U.S.C. 112 first paragraph, because the claimed invention is not supported by either a substantial utility or a well established utility, for the reasons stated in the Office Action of 7/28/06 and for the reasons set-forth below.

The claims are drawn to isolated antibodies or antibody fragments that bind specifically to a protein encoded by polynucleotide SEQ ID NO:1 or to fragments of a

protein encoded by SEQ ID NO:1 and a method for binding said antibodies to said protein or to fragments of said protein.

As stated in the Office Action of 7/28/06, the specification does not teach the protein sequence or the open reading frame of SEQ ID NO:1. Thus, the specification does not provide enough information to indicate for which proteins the claimed antibodies are specific. Therefore, the specification clearly does not describe a utility for antibodies with unknown specificity.

In response to the Office Action of 7/28/06, Applicant amended the pending claims to indicate that the claimed antibodies bind "a" or "the" "native" protein encoded by SEQ ID NO:1. Applicant cites MPEP 2107.02 and argues that Examiner has provided no evidence to support the statement that one of skill in the art would doubt any truth to a stated utility of the claimed invention. Applicant further states that express teachings in the specification of native protein encoded by SEQ ID NO:1 is not required to meet the requirements of 35 U.S.C. 101 and 35 U.S.C. 112l. Rather, Applicant states that MPEP 2107.01 indicates that an applicant must claim an invention that is statutory subject matter and must show that the claimed invention is useful for some purpose either expressly or implicitly. Applicant argues that the sequence of native protein encoded by SEQ ID NO:1 is implicit in the teachings of the specification. Applicant further argues that the sequence of native protein encoded by SEQ ID NO:1 is implicit in the teachings of the specification especially in light of the general knowledge in the art for identifying open reading frames of polynucleotide sequences. In arguing the credibility of the asserted utility, Applicant further states the logic underlying the

asserted utility is not flawed and the facts upon which the assertion is based are not inconsistent with the logic underlying the assertion. Applicant further states that the asserted utility has been confirmed in previously submitted publications.

The amendments to the claims and the arguments found in the response of 3/28/07 have been carefully considered, but are not deemed persuasive. In regards to the amendments to the claims, term "native" does not further clarify which protein the claimed antibody is specific. In regards to the argument that Examiner has provided no evidence to support the statement that one of skill in the art would doubt any "truth" to a stated utility of the claimed invention, the "truth" of the asserted utility is doubted since the asserted utility could not be performed because reagents required for said utility are not disclosed either expressly or implicitly. In regards to the argument that the sequence of native protein encoded by SEQ ID NO:1 is implicit in the teachings of the specification and/or in the teachings of the specification in light of the art, the sequence of proteins encoded by SEQ ID NO:1 are not implicit in the teachings of the specification and/or in the teachings of the specification in light of the art for the reasons found in the Office Action of 3/28/07. There were routinely-used methods at the time of filing that would have enabled one of skill in the art to identify *potential* open reading frames from an mRNA sequence. However, as indicated in the figures provided with the Declaration, Applicants would identify multiple open reading frames using tools described in the art with SEQ ID NO:1. One of skill in the art would have no reason to assume that the largest open reading frame identified by a computer program would be *the* protein encoded by SEQ ID NO:1. From the information provided in the

specification, there is no reason to believe that the protein of SEQ ID NO:1 would not be encoded by other smaller open reading frames diagramed in the Declaration's figures. Therefore, since the specification does not identify "a protein encoded by polynucleotide SEQ ID NO:1", it cannot be determined to what the claimed antibody or antibody fragment will bind. Further, although Tringler and Salceda demonstrate utility of an antibody against "a" protein of SEQ ID NO:1, the specification did not teach "the" protein of SEQ ID NO:1. Therefore, utility of an antibody specific for a protein that the specification did not adequately describe is irrelevant. Essentially, the specification does not describe what the protein *is*. Thus, there is no utility for the claimed antibodies, antibody fragments, or methods of using said antibodies or said antibody fragments. In regards to the argument that the logic underlying the asserted utility is not flawed and the facts upon which the assertion is based are not inconsistent with the logic underlying the assertion, the logic underlying the asserted utility is flawed because reagents required for said utility are not disclosed either expressly or implicitly for the reasons found in the Office Action of 3/28/07 and for the reasons stated above.

35 USC § 112, first paragraph (Written Description Rejection)

The rejection of claims 14, 21-28, and 35-49 under 35 U.S.C. 112 first paragraph, for failing to comply with the written description requirement, is maintained for the reasons stated in the Office Action of 7/28/06 and for the reasons set-forth below.

The claims are drawn to isolated antibodies or antibody fragments that bind specifically to a protein encoded by polynucleotide SEQ ID NO:1 or to fragments of a

protein encoded by SEQ ID NO:1 and a method for binding said antibodies to said protein or to fragments of said protein.

As stated in the Office Action of 7/28/06, the specification does not teach the protein sequence or the open reading frame of SEQ ID NO:1. Thus, the specification does not provide enough information to indicate for which proteins the claimed antibodies are specific. Without identifying for which proteins the claimed antibodies are specific, the antibodies lack a written description, as the specification does not disclose identifiable structural or functional attributes of said antibodies.

In response to the Office Action of 7/28/06, Applicant amended the pending claims to indicate that the claimed antibodies bind "a" or "the" "native" protein encoded by SEQ ID NO:1. Applicant further argues that SEQ ID NO:1 includes classical structural characteristics, well established in the art, which define the open reading frame of a nucleic acid sequence which encodes "the" native protein. Applicant further states that the disclosure includes various methods of making and using antibodies. Applicant further states that any requirement for an explicit description in the specification of the amino acid sequence of the native protein encoded by SEQ ID NO:1 to meet the written description requirement, when the disclosed structural characteristics of polynucleotide SEQ ID NO:1 coupled with detailed teachings of methods for production and use of the claimed antibodies is unwarranted. Applicant further states that the Declaration by Susana Salceda makes clear that while every nuance of the protein sequence and/or open reading frame of SEQ ID NO:1 may not have been explicitly described in the specification, sufficient distinguishing

characteristics were taught in the specification so that using standard knowledge of those skilled in the art as of the filing date of the instant application this information could be routinely determined. Applicant concludes that a written description question should not be raised in the instant case since the original claims were drawn to antibodies and the specification discloses a method of making the claimed invention and function of the invention. Applicant further states that absence of details of the coding region or the encoded protein should not be the basis of this rejection since the encoded native protein could be routine determined based upon the disclosure of SEQ ID NO:1.

The amendments to the claims and the arguments found in the Response of 3/28/07 have been carefully considered, but are not deemed persuasive. In regards to the amended claims reciting "a" or "the" "native" protein encoded by SEQ ID NO:1, the term "native" does not further clarify the structure and/or the function of polypeptides encoded by undisclosed regions of SEQ ID NO:1 or antibodies that bind said polypeptides. In regards to the argument that SEQ ID NO:1 includes classical structural characteristics, well established in the art, which define the open reading frame of a nucleic acid sequence which encodes "the" native protein and the sequence of native protein encoded by SEQ ID NO:1 is implicit in the teachings of the specification and/or in the teachings of the specification in light of the art, the sequence of proteins encoded by SEQ ID NO:1 are not implicit in the teachings of the specification and/or in the teachings of the specification in light of the art for the reasons found in the Office Action of 3/28/07. There were routinely-used methods at the time of filing that would have

enabled one of skill in the art to identify *potential* open reading frames from an mRNA sequence. However, as indicated in the figures provided with the Declaration, Applicants would identify multiple open reading frames using tools described in the art with SEQ ID NO:1. One of skill in the art would have no reason to assume that the largest open reading frame identified by a computer program would be *the* protein encoded by SEQ ID NO:1. From the information provided in the specification, there is no reason to believe that the protein of SEQ ID NO:1 would not be encoded by other smaller open reading frames diagramed in the Declaration's figures. Therefore, since the specification does not identify "a protein encoded by polynucleotide SEQ ID NO:1", it cannot be determined to what the claimed antibody or antibody fragment will bind. The disclosure of various methods of making and using antibodies does not provide structural or functional or functional information to indicate that Applicant was in possession of the claimed antibodies. Structural features that could distinguish the compounds of the claimed genus from others not encompassed by the genus are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is needed.

New Rejections Necessitated by Amendments

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-28, 35-41, and 44-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24, 28, 38-40, and 44-46 and dependent claims 25-27, 35-37, 41, and 47-49 are rejected because claims 24, 28, 38-40, and 44-46, recite the limitation "the native protein...". There is insufficient antecedent basis for this limitation in the claim. Claims 24, 28, 38-40, and 44-46 recite or make reference to “a” native protein; however, it is unclear which “native” protein is “the” native protein.

Summary

No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

SHANON FOLEY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600